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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,048	08/23/2001	C. Frank Bennett	ISPH-0567	1653
7590 12/15/2003			EXAMINER	
Jane Massey Licata Licata & Tyrrell P.C. 66 E. Main Street Marlton, NJ 08053			MCGARRY, SEAN	
			ART UNIT	PAPER NUMBER
			1635	

DATE MAILED: 12/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/938,048

Applicant(s)

BENNETT ET AL.

Examiner

Sean R McGarry

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4-8 and 10-14 is/are pending in the application.
- 4a) Of the above claim(s) 12-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-8, 10 and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Applicant asserts that the examiner has made an error in the Office Action mailed 6/27/03 by withdrawing claims 12-14. Applicant asserts that Group I includes Claims 1-15. This is true, however, claims 12-14 were withdrawn as being non-elected **species** within Group I. See page 2 of the Official Action mailed 6/27/03.

Claims 1, 2, 4-8, 10, and 11 are under examination, claims 12-14 are withdrawn from consideration , and claims 3, 9, and 15-29 have been canceled.

Claims 1, 2, 5, 6 and 10, and 11 remain, and claim 4 is rejected under 35 U.S.C. 102(b) as being anticipated by Baker et al [US 6,080,580]. This rejection is maintained for the same reasons set forth in the Official Action mailed 6/27/03.

The instantly claimed invention is drawn to a method for (1) identifying a gene involved in a response to a stimulus where the method comprises contacting cells with antisense from a library prior to the application of a stimulus, (2) where the response can be secretion of a compound (3) where the compound is a cytokine (4) the response is modulation of inflammation and where the response is inhibited.

Baker et al have disclosed the use of antisense from a library of antisense (see Table 1, Table 2 and Table 3, for example) targeted to TNF- α (a cytokine) which is involved in inflammation response (an inhibition of TNF- α correlates to an inhibition of a cellular inflammatory response (see column 1, for example). It has been disclosed in

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columns 19-20 a method wherein various antisense oligonucleotides (from a library) were added to different subpopulations of NeoHK cells (see also Table 3, for example). The cells were then treated with growth factors. After treatment the expression of TNF- α and the secretion of THF- α was measured. It is clear from Tables 2, 3, 5, 7 and 8 that the response to the stimulus expression of TNF- α mRNA and secretion of TNF- α secretion were variably stimulated and inhibited based on the conditions used and the particular antisense used, for example.

Claims 1, 2, 7, 8, 10, and 11 remain rejected under 35 U.S.C. 102(b) as being anticipated by Bennett et al [US 5,514,788].

Bennett et al have disclosed the use of antisense targeted to various cell adhesion molecules, which are involved in inflammation. Inhibition of cell adhesion molecules inhibits inflammatory response of cells, for example (see columns 1-2, for example) Bennett et al have disclosed the inhibition of adhesion proteins such as ICAM, VCAM and ELAM with antisense oligonucleotides from antisense libraries defined in Tables 1, 2, 3, and 4, for example. It has been disclosed in Example 1 VCAM, ICAM, and ELAM expression is measured after cells (subpopulations) were treated with antisense to various cell adhesion molecules prior to challenge of the cells to various cytokines. It can be seen in tables 3, 5, 4 and Example 6 the stimulation and inhibition of cell adhesion molecule expression in response to the application of various cytokines under various conditions, for example.

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In response to applicant's arguments, filed 9/25/03, the recitation "a method for identifying one or more genes involved in an inflammatory response by a cell" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

It is noted that the prior art discloses each and every step recited in the instant claims. Further the instant claims require in step b) of claim 1, for example, "determining which antisense oligonucleotide [targeted to a known cytokine or growth factor] within the library modulate said inflammatory response wherein antisense oligonucleotides which modulate. ...correspond to gene products involved in said inflammatory response." It is unclear how the prior art differs from the claimed invention based on applicants assertion that the intention claimed invention of the method is different than the prior art. The prior art clearly discloses the methods steps recited in the instant claims. The instant claims fail to provide any steps that would define over the disclosure of the prior art. Applicant has not shown that the method steps instantly recited define over the teachings of the prior art.

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Any rejection made in a previous Official Action and not repeated herein is withdrawn.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean R McGarry whose telephone number is (703)305-7028. The examiner can normally be reached on M-Th (6:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703) 308-0447. The fax phone

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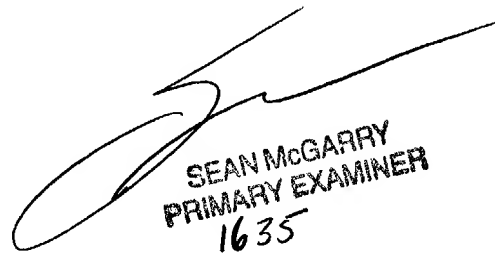
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number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

srm



SEAN MCGARRY
PRIMARY EXAMINER
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